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EXAMINER	
CALDWELL, SUSAN K	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,191	BACK ET AL.	
	Examiner	Art Unit	
	SUSAN CALDWELL	4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/7/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *7 and 10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9 and 16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/17/05,9/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-9 and 16-20, in the reply filed on 4/24/2009 is acknowledged. The traversal is on the ground(s) that the claims do provide a contribution over the prior art, in spite of the citation of the Journal of Food Science, Vol.41, 1976 as cited in prior art (see Abstract on page 57; page 61, first paragraph under heading "Protein and solids recovery"). This is not found persuasive because of the following:

The claims filed on 3/17/2005 were considered for examination purposes and at that time a restriction was considered proper because of the International Preliminary Examination Report, which was based on the same claims presented before this Office. It should also be noted that since 3/17/2005, there was no preliminary amendment filed in this case amending any claims. However, upon receiving the Restriction Requirement, applicant has amended the claims to claim only the narrower embodiment of an oilseed, lupine, and then argues that the reference to Journal of Food Science, Vol.41, 1976, does not apply to the instant claims because of the use of lupine seeds therein.

Since the instant claims were not before the Examiner at the time the Restriction was made, reconsideration of the claims for restriction purposes was

again undertaken and it has been determined that the special feature linking the two inventions does not provide a contribution over the art as evidenced by Journal of Food Science, Vol.41, 1976.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim **16** recites the limitation "biotechnological treatment of a predominantly or exclusively source plant material" in lines 2 and 3, which is indefinite because it lacks antecedent basis. Also, it is not clear what "biotechnological treatment" includes. "Predominantly or exclusively source plant" is indefinite because "predominantly or exclusively" does not properly define what is intended with reference to the plant material. The independent

claim 1 cites “plant source”; claim 16 states “source plant”, thus “source plant” lacks proper antecedent basis.

Claim **17** recites the limitation "suitable manner" in the third line of claim 17. “Suitable manner” is of indeterminate scope and it is unclear what it defines. It is unclear whether “fermented” refers to the protein preparation or plant source. The independent claim 1 recites “plant source”; claim 17 states “source plant”, which depends on claim 1, thus “source plant” lacks proper antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-6, 8-9 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall et al. (U.S. Patent No. 4,678,673) ("Marshall"), and further in view of Holley et al. (U.S. Patent No. 7,074,449) ("Holley").

Regarding claims **1-3**, Marshall teaches oilseed products that are fermented with microorganisms including *L. case,* which produces diacetyl and acetylmethycarbinol(AMC); the fermented oilseed products have a buttery or dairy-like flavor (i.e. milk-like aroma) and are useful in preparing imitation dairy products such as imitation cream cheese products, i.e., yogurt, cheese, ice cream and other dairy products, derived from oilseed components as milk or caseinate replacers (Abstract; col. 1, lines 5-13). The dairy-like flavors are the result from the bacterial production of two compounds namely diacetyl and AMC, which are produced in soymilk (col. 1, lines 43-50). Marshall also teaches fermentation process for manufacturing dairy-like products from a variety of vegetable oilseeds, such as peanut, cottonseed, rapeseed, sunflower seed and soybean, and mixtures thereof (col. 3, lines 52-60). Marshall cites that diacetyl, ACM, including lactic acid, are compounds producing the buttery, milk-like flavors in milk products, which are produced by the fermentation of the oilseeds (col. 7, lines 1-6, 30-38;

col. 8, lines 8-49; col. 10, lines 44-59). Marshall mentions diacetyl but he does not specifically show 1ppm, 7ppm, 15ppm of diacetyl. Diacetyl inherently produces milk-like aroma and it would have been obvious to add the sufficient amount of diacetyl to produce the desired degree of aroma, i.e. stronger diacetyl content will create more milk-like aroma. Marshall teaches protein preparation produced to a level of 96% total solids made from soybeans (col. 5, lines 39-62; col. 8, lines 1-3; col. 14, lines 5-10 (claim 3)). Marshall teaches oilseed preparations and mentions a variety of other types of oilseeds that are used, but he does not specifically mention lupine seeds, although lupine seeds are inherently an oilseed.

Holley teaches processing alkaloid, oil and protein preparations from protein-containing lupine seeds, which are similar to soybeans, in protein composition, crude fiber fraction and oil concentration (col. 1, lines 15-27). In addition, lupines have additional benefits that it can be grown in regions unsuitable for soy beans, such as Western Europe or Australia (col. 1, lines 27-32), as well as economically more available, as the extracted alkaloids from lupines may be selectively employed as active ingredients in agriculture and in the pharmaceutical industry (col. 1, lines 33-44). Holley also teaches the use of any protein and oil or starch containing seed in addition to the lupine seed, such as rape, linseed or leguminous plants, particularly soy-beans, peanuts, peas and horse beans (col. 3,

lines 1-4). Holley teaches protein productions with a level of dry solids of at least 12%, a protein level in the dry solids of more than 70%, preferably higher than 85%, and an alkaloid percentage of less than 0.5%, preferably 0.1% in the dry solids (col. 4, lines 54-61). Although Holley does not mention fermenting lupine seeds with a lactic acid producing microorganism, such as *Lactobacillus caseissprhamnosus,* since lupine seeds are also oilseeds, fermenting lupine seeds with a microorganism, *L.casei,* as disclosed by Marshall can be reasonably expected to produce diacetyl and lactic acid creating a milk-like aroma, as taught by Marshall. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made, to use lupine seeds instead of Marshall's oilseeds for the benefits taught by Holley as enumerated above, and modify the reactants (i.e. lupine seeds and L. casei amounts) to produce the required amounts of diacetyl, lactic acid, to produce the desired milk-like aroma in the protein preparations for optimal product, i.e., food product, pharmaceutical product, or probiotic nutraceutical, that will have beneficial organoleptic properties for the consumer.

With regard to the claimed amounts of diacetyl, since this compound produces a milk-like aroma, then to determine and use amounts based on its desired effect would have been prima facie obvious to the skilled worker, since the

discovery of an optimum value of a known result effective variable, without producing any new or unexpected results, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980) (see MPEP § 2144.05, II).

Regarding claim **4**, Marshall is taken as cited above; L-lactic acid is one of two optical isomers of lactic acid predominantly produced by pyruvate (Wikipedia definition of L-lactic acid), and is an inherent component of lactic acid. Marshall teaches fermentation process to stimulate flavor production with *L. casei* organism in the presence of pyruvate, acetate or citrate (col. 10, lines 17-35).

Regarding claim **5**, Marshall is taken as cited above; protein preparation made from lupine seeds, which is a plant source and an oilseed, has inherent properties such as, lactose-free and cholesterol-free.

Regarding claim **6**, Marshall teaches fermentation process which is carried out by specific microorganisms, particularly *Lactobacillus caseisprhamnosus* among others, which produce diacetyl and lactic acid, that convert compounds in the oilseed products to desirable, dairy-like products (col. 2, lines 18-37; col. 6, Table II; col. 7, lines 30-62, Table III; col. 8, lines 21-34).

Regarding claims **8-9** and **21,** Marshall teaches imitation dairy products (e.g. protein preparation from oilseed, such as soy beans) which further comprises

additional food, flavoring, and functional components such as non-fat dry milk, stabilizers (e.g. carob bean gum), emulsifiers (e.g. mono and diglycerides of edible fatty acids), melting salts (e.g. sodium citrate), flavor agents and food grade acids (e.g. lactic acid) that may be utilized, alone or in combination to provide desirable flavor, texture, other properties, and they may be utilized at weight percent levels based on the total weight of the imitation diary product (col. 3, lines 7-34). Marshall teaches that the most effective fermentation pH range should be carried out between pH 6.0 and 7.0 (col. 5, lines 1-8). Regarding the properties of the protein preparation recited at claims 8-9 and 21 such as the emulsifying activity of the protein preparation at various strengths that applicant has recited, these are properties of the protein preparation and it is being held that the combination of references renders such properties obvious and would have been obvious to the skilled worker who would substitute the oilseed of Holley with that of Marshall.

For the reasons discussed above, it would have been obvious to a person of ordinary skill in the art at the time of the invention to substitute soybeans with lupine seeds, and in doing so, the properties of emulsifying and foaming activity would have been rendered obvious.

Regarding claim **16**, Marshall teaches that diacetyl, ACM, including lactic acid, are compounds producing buttery, milk-like flavors in milk products, which are produced by the fermentation of oilseeds (col. 7, lines 1-6, 30-38; col. 8, lines 8-49; col. 10, lines 44-59) by microorganisms.

Regarding claim **17**, Marshall teaches the fermentation process starting from a dry, clean, whole soybeans, grinding, pretreating, pasteurizing, adding sodium acetate, fermenting with *L. casei* culture, drying, producing to a level of 96% total solids (col. 3, line 60 through col. 4, line 50; col. 5, lines 39-62). He teaches that the fermentation process may be enhanced by selecting fermentation enhancing agents or as a concentrated paste harvested from milk medium and stored in liquid nitrogen (col. 4, lines 58-69). In addition, Marshall teaches the fermentation process to stimulate flavor production with *L. casei* organism in the presence of pyruvate, acetate or citrate as additives (col. 10, lines 17-35, 44-66). Claim 17 is written in a product-by-process format and as such, it is the novelty of the instantly claimed product that needs to be established and not that of the recited process steps. *In re Brown*, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 191 USPQ (CCPA 1976). The product claimed in claim 17 therefore, has been addressed above.

Regarding claims **18-20**, Marshall teaches fermented oilseed products that are useful in imitation dairy food products, which includes ice cream, cream cheese, yogurt (i.e. probiotic food), sour cream, soymilk, cheese spreads, dips, among others (col. 1, lines 34-42; col. 2, lines 23-26). Probiotic foods recited in instant claim 19 are rendered obvious by Marshall's disclosure of yogurt. The preponderance of oilseeds that are disclosed by Marshall as producing diacetyl upon fermentation with the same microorganism and the inclusion of lupine in Holley's disclosure of oilseeds, having its own benefits, renders the use of lupine seeds in Marshall's invention obvious, barring any evidence that shows otherwise.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN CALDWELL whose telephone number is (571)270-7870. The examiner can normally be reached on Monday - Friday EST, 7:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, KEITH HENDRICKS can be reached on (571)272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/
Primary Examiner, Art Unit 1794

SC